## REMARKS

This Response is submitted in reply to the Final Office Action mailed on June 24, 2008. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-626 on the account statement.

Claims 1-13 are pending in the application. In the Office Action, Claim 13 is rejected under U.S.C. §112, second paragraph and Claims 1-12 are rejected under 35 U.S.C. §103. In response, Applicants have amended Claim 1 and 13 and canceled Claim 4. This amendment does not add new matter and is supported in the specification (Preliminary Amendment) at page 9, lines 7-8 and page 16, lines 24-26. In view of the amendment and for at least the reasons set forth below, Applicants respectfully submit that the rejections should be withdrawn.

In the Office Action, Claim 13 is rejected under 35 U.S.C. §112, second paragraph. The Office Action states that it is unclear what 0.5-3.5% L-(+) lactic acid is based on (e.g. weight or volume) and whether it is a percentage of the initial powdered product or of the final liquid state. In response, Applicants amend Claim 13 to recite, the nutritional formula according to claim 1, wherein the nutritional formula comprises 0.5-3.5% by weight L(+)- lactic acid, based on the dry weight of the nutritional formula. As amended, Applicants submit that Claim 13 meets all the requirements under the second paragraph of 35 U.S.C. §112. Accordingly, Applicants respectfully request that the rejection be withdrawn.

In the Office Action, Claims 1, 2 and 7-13 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 96/31130 to Mazer et al. (*"Mazer"*) in view of WHO (Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, "Lactic acid and its ammonium, calcium, potassium, and sodium salts", World Health Organization Technical Report Series, 1974, No. 539) (*"WHO"*). Independent Claim 1 recites, in part, a nutritional formula comprising a protein source, a carbohydrate source and a lipid source and comprising lactic acid and at least 70% by weight of the lactic acid is present as the enantiomer of L(+)-lactic acid, the formula is directly acidified. Independent Claims 7, 10 and 11 recite, in part, a method of preparing nutritional formulas comprising the step of directly acidifying the nutritional formula by using L(+)-lactic acid. Applicants submit that the cited references, alone or in combination, fail to disclose or suggest every element of the rejected claims.

*Mazer* fails to disclose or suggest a nutritional formula comprising a protein source, a carbohydrate source and a lipid source as required, in part, by independent Claim 1. Instead, *Mazer* teaches a beverage made by reconstituting beverage concentrates and additives to make a liquid nutritional product fortified with both calcium and vitamin D. In fact, *Mazer* provides a nutritional profile for the prototype low pH beverages in accordance with the invention that has a protein level of 0%. See, *Mazer*, Table 23. Therefore, *Mazer* clearly fails to teach or suggest a formula comprising a protein source, a carbohydrate source and a lipid source.

*Mazer* also fails to disclose or suggest a formula directly acidified with an enantiomer of L(+)-lactic acid as required by Claim 1 or directly acidifying a nutritional formula with L(+)-lactic acid as required by method Claims 7, 10 and 11. Though the Office Action asserts that *Mazer* teaches the use of purified lactic acid as an acidulant in beverages and beverage concentrates, this "purified lactic acid" is actually a fermented lactic acid. See, *Mazer*, page 34. By contrast, the present claims teach direct acidification such that a fermentation process does not produce the L(+)-lactic acid. See, specification, page 6, lines 15-18.

By avoiding the fermentation step, the optional drying process will be much more efficient, due to the fact that a fermentable solution with low dry-matter content may be avoided. The whole process may be conducted at higher dry matter, thus superseding an evaporation step or drying of a solution at a high water content. See, specification, page 9, lines 1-4. Moreover, by directly acidifying using an enantiomer of L(+)-lactic acid, one can produce nutritional formulas having bacteriostatic activity while being nutritionally safe for infants. See, specification, page 5, lines 10-12.

The Office Action asserts, however, that *Mazer* teaches the use of lactic acid (88%) for use in the invention and that one of ordinary skill the art would recognize that lactic acid (88%) would be a product such as PURAC FCC 88 comprising L(+) lactic acid product prepared by fermentation. See, Office Action, page 7, ¶32. Applicants respectfully disagree. First, the Office Action admits that *Mazer* fails to disclose or suggest any use of L(+) lactic acid in its beverage. See, Office Action, page 4, ¶13. Moreover, simply disclosing the use of lactic acid (88%) does not make it obvious to one skilled in the art that this disclosure refers to L(+)-lactic acid. Beside L(+)- lactic acid, general "lactic acid" could refer, for example, to a racemic of lactic acid and another acid, potassium lactate, sodium lactate, D(-)- lactate, DL-lactic acid, or

D(-) lactic acid. Therefore, nothing in *Mazer* even suggests that "lactic acid (88%)" is L(+)-lactic acid as required by the claims.

Applicants also submit that *WHO* fails to remedy the deficiencies of *Mazer*. Like *Mazer*, *WHO* fails to disclose or suggest a nutritional formula comprising a protein source, a carbohydrate source and a lipid source as required, in part, by independent Claim 1. In fact, the Office Action relies upon *WHO* to disclose use of L(+)- lactic acid.

*WHO* also fails to disclose or suggest a formula directly acidified with an enantiomer of L(+)-lactic acid as required by Claim 1 or directly acidifying a nutritional formula with L(+)-lactic acid as required by method Claims 7, 10 and 11. Instead, the Office Action only relies on *WHO* arguably to disclose L(+)-lactic acid rather than a direct acidification step. See, Office Action, page 4, ¶14. Moreover, *WHO* teaches acidifying with general DL-lactic acid and not direct acidification with a specific L(+)-lactic acid. See, *WHO*, page 5.

Further, *WHO* also fails to disclose or suggest use of L(+)-lactic acid. The Office Action asserts, however, that because *WHO* teaches that DL-lactic acid and D(-) lactic acid should not be used in infant foods, this only leaves L(+) lactic acid for use in infant foods. See, Office Action, page 4, ¶14. Applicants respectfully submit that this assertion misinterprets DL-lactic acid. DL-lactic acid is a racemic mixture of L(+) and D(-) lactic acid forms. As a result, because the experiments in *WHO* show that infants had difficulty utilizing DL and D(-) lactic acids, infants inherently had difficulty utilizing both L(+) and D(-) lactic acid forms. Therefore, no part of *WHO* teaches that infants can positively utilize L(+) lactic acid. Instead, based on the negative results of the racemic DL lactic acid, *WHO* actually teaches away from using L(+) lactic acid in nutritional compositions.

The Office Action further asserts, however, that food-grade lactic acids available are primarily L-(+) lactic acids. See, Office Action, page 8, ¶34. However, as stated above, "lactic acid" is not such a limited category and can include other lactic acids such as, for example, a racemic of lactic acid and another acid, potassium lactate, sodium lactate and D(-)- lactate, as well as the DL-, D(-) and L(+)-lactic acids discussed. Moreover, as also stated above, because DL lactic acid includes L(+) lactic acid, an enantiomer of L(+)-lactic acid, *WHO* actually teaches away from using the lactic acid recited in the claims. In fact, the Office Action has submitted no

evidence that *WHO*, by teaching away from using DL lactic acid, is actually teaching or suggesting the use of L(+) lactic acid, a subcomponent of DL lactic acid.

Accordingly, *WHO* fails to remedy the deficiencies in *Mazer* because (a) *WHO* fails to disclose or suggest a formula comprising a protein source, a carbohydrate source and a lipid source as required by Claim 1, (b) a formula or method for direct acidification using L(+)-lactic acid as required by the present claims and (c) the use of L(+)-lactic acid in nutritional formulas or methods. *Who* actually teaches away from using L(+)-lactic acid in nutritional formulas.

Therefore, the combination of *Mazer* in view of *WHO* fails to disclose or suggest every element of the present claims.

In the Office Action, Claims 1, 3-6 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over (Schwartz, A.B. 1926, "The Use of Lactic Acid Milk in Infant Feeding", The American Journal of Nursing, Vol. 26, No. 12, pp. 927-932) (*"Schwartz"*) in view of *WHO* with additional evidence provided by Wong et al. (1999, Fundamentals of Dairy Chemistry, 3rd Edition, pp.1, 82-83, Springer – Verlag) (*"Wong"*). Applicants respectfully submit that the cited references, alone or in combination, fail to disclose or suggest every element of the rejected claims.

*Schwartz* fails to disclose or suggest a formula directly acidified with an enantiomer of L(+)-lactic acid as required, in part, by Claim 1. The Office Action admits the same. See, Office Action, page 5, ¶20. As stated previously, *WHO* fails to remedy this deficiency with regard to an L(+)-lactic acid because (a) *WHO* fails to disclose or suggest a formula for direct acidification using an enantiomer of L(+)-lactic acid and (b) *WHO* fails to disclose or suggest the use of an enantiomer of L(+)-lactic acid in nutritional formulas and actually teaches away from using L(+)-lactic acid in nutritional formulas. Moreover, *Wong* also fails to remedy this deficiency as the Office Action only relies on *Wong* arguably to disclose proteins comprising whey protein and casein. See, Office Action, page 5, ¶19.

The Office Action asserts again that because *WHO* specifically states neither D(-)- nor DL lactic acid should be used in infant foods, one of ordinary skill would recognize that L-(+) lactic acid is the obvious choice for inclusion in the infant formula. See, Office Action, page 9, ¶36. However, as stated above, "lactic acid" is not such a limited category and can include other lactic acids such as, for example, a racemic of lactic acid and another acid, potassium lactate,

sodium lactate and D(-)- lactate, as well as the DL-, D(-) and L(+)-lactic acids discussed. Moreover, as also stated above, because DL lactic acid includes L(+) lactic acid, an enantiomer of L(+)-lactic acid, *WHO* actually teaches away from using the lactic acid recited in the claims. In fact, the Office Action has submitted no evidence that *WHO*, by teaching away from using DL lactic acid, is actually teaching or suggesting the use of L(+) lactic acid, a subcomponent of DL lactic acid.

The Office Action also asserts that one of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L(+) as evidenced by PURAC literature. See, Office Action, page 9, ¶36. Applicants respectfully disagree and submit that PURAC is obviously just showing one example of food-grade lactic acid. As stated above, there are many food-grade lactic acids such as, for example, a racemic of lactic acid and another acid, potassium lactate, sodium lactate and D(-)- lactate, as well as the DL-, D(-) and L(+)-lactic acids discussed.

Therefore, the combination of *Schwartz* in view of *WHO* and *Wong* fails to disclose or suggest every element of the present claims.

In the Office Action, Claims 1 3-6 and 12 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,212,893 to Takahata (*"Takahata"*) in view of *WHO* with additional evidence provided by *Wong*. Applicants respectfully submit they the cited references, alone or in combination, fail to disclose or suggest every element of the rejected claims.

*Takahata* fails to disclose or suggest a formula directly acidified with an enantiomer of L(+)-lactic acid as required by Claim 1. The Office Action admits the same. See, Office Action, page 6, ¶27. As stated previously, *WHO* fails to remedy this deficiency with regard to L(+)-lactic acid because (a) *WHO* fails to disclose or suggest a formula for direct acidification using an enantiomer of L(+)-lactic acid and (b) *WHO* fails to disclose or suggest the use of an enantiomer of L(+)-lactic acid in nutritional formulas and actually teaches away from using L(+)-lactic acid in nutritional formulas. Moreover, *Wong* also fails to remedy this deficiency as the Office Action only relies on *Wong* arguably to disclose proteins comprising whey protein and casein. See, Office Action, page 6, ¶26.

In response, the Office Action again makes the same assertions regarding *WHO* as it did for the above rejections. Specifically, the Office Action notes that because *WHO* specifically states neither D(-)- nor DL lactic acid should be used in infant foods, one of ordinary skill would

recognize that L-(+) lactic acid is the obvious choice for inclusion in the infant formula. The Office Action also asserts that one of ordinary skill would further recognize that food-grade lactic acid is commonly sold as 95% L(+) as evidenced by PURAC literature. See, Office Action, page 10, ¶38. Applicants, again, disagree with these assertions for at least the reasons discussed previously.

Therefore, the combination of *Takahata* in view of *WHO* and *Wong* fails to disclose or suggest every element of the present claims.

Accordingly, Applicants respectfully request that the obviousness rejections of Claims 1-13 be withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same.

Respectfully submitted,

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